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No. 76-686

In the Supreme Court of the United States

OCTOBER TERM, 1976

ELIZABETH DALEY, M.D., PETITIONER

v.

JOSEPH A. CALIFANO, JR., SECRETARY OF HEALTH, EDUCATION AND WELFARE, ET AL.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT

BRIEF FOR THE RESPONDENTS IN OPPOSITION

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OPINIONS BELOW

The opinion of the court of appeals (Pet. App. 1a-6a) is reported at 536 F. 2d 519. The memorandum and order of the district court (Pet. App. 7a-18a) are reported at 400 F. Supp. 1288.

JURISDICTION

The judgment of the court of appeals was entered on May 27, 1976.[1] A timely petition for rehearing was denied on July 20, 1976 (Pet. App. 21a). A petition for

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[1]The appendix to the petition does not include a copy of the judgment, as required by Rule 23.1(j) of the Rules of this Court.

a writ of certiorari was filed on October 18, 1976.[2] The jurisdiction of this Court is invoked purusant to 28 U.S.C. 1254(1).

QUESTION PRESENTED

Whether petitioner's complaint for declaratory and injunctive relief, based on a claim that Section 704(a) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 374(a), does not authorize the Food and Drug Administration to inspect the offices at which she conducts her medical practice, was sufficiently ripe for adjudication.

STATUTES INVOLVED

The relevant portions of 21 U.S.C. 331 and 333 (Sections 301 and 303 of the Federal Food, Drug, and Cosmetic Act, 52 Stat. 1042, 1043, as amended), are printed at Pet. 6. The relevant portion of 21 U.S.C. 374(a) (Section 704(a) of the Act, 52 Stat. 1057, as amended by Pub. L. 94-295, Sec. 6, 90 Stat. 581) provides:

> For purposes of enforcement of this chapter, officers or employees duly designated by the Secretary, upon presenting appropriate credentials and a written notice to the owner, operator, or agent in charge, are authorized (1) to enter, at reasonable times, any factory, warehouse, or establishment in which food, drugs, devices, or cosmetics are manufactured, processed, packed, or held, for introduction into interstate commerce or after such introduction, * * * and (2) to inspect, at reasonable times and within reasonable limits and in a reasonable manner, such factory,

[2] The Court received the petition on October 18, 1976, but it was returned to counsel for reprinting. The petition was again received on November 17, 1976, and docketed as of the date of the original submission.

> warehouse, establishment, * * * and all pertinent equipment, finished and unfinished materials; containers, and labeling therein. In the case of any factory, warehouse, establishment, or consulting laboratory in which prescription drugs or restricted devices are manufactured, processed, packed, or held, the inspection shall extend to all things therein (including records, files, papers, processes, controls, and facilities) bearing on whether prescription drugs or restricted devices which are adulterated or misbranded within the meaning of this chapter, or which may not be manufactured, introduced into interstate commerce, or sold, or offered for sale by reason of any provision of this chapter, have been or are being manufactured, processed, packed, transported, or held in any such place, or otherwise bearing on violation of this chapter. * * * The provisions of the second sentence of this subsection shall not apply to—
>
> * * * * *
>
> (2) practitioners licensed by law to prescribe or administer drugs, or prescribe or use devices, as the case may be, and who manufacture, prepare, propagate, compound, or process drugs, or manufacture or process devices, solely for use in the course of their professional practice;
>
> * * * * *

21 U.S.C. 332(a) (Section 302(a) of the Act, 52 Stat. 1043, as amended) provides in pertinent part:

> The district courts of the United States * * * shall have jurisdiction * * * to restrain violations of [21 U.S.C. 331] * * *.

STATEMENT

Petitioner is a physician who specializes in the treatment of arthritis (Pet. App. 3a). Affidavits submitted by respondents in support of their motion for summary judgment showed that in September 1974, the Food and Drug Administration ("FDA") received information that petitioner had received or was receiving shipments of a dangerous and illegal drug known as Liefcort for use in the treatment of her patients. FDA files indicated that the drug Liefcort is an irrational mixture of potent hormones, and that serious adverse effects have been attributed to the use of the drug.

After a preliminary investigation by FDA's New York District Office indicated that petitioner was distributing the drug involved, a formal inspection[3] of petitioner's premises was ordered.

[3]21 U.S.C. 374(a) authorizes FDA officials, upon presenting appropriate credentials and a written notice to the owner, operator or agent in charge, to enter, at reasonable times, any establishment in which drugs or devices are manufactured, processed, packed or held, for introduction into interstate commerce or after such introduction, and to inspect at reasonable times, and within reasonable limits and in a reasonable manner, such establishment and all pertinent equipment, finished and unfinished materials, containers and labeling in the establishment. Section 374 also provides additional inspection authority with respect to prescription drugs, which extends to records, files, processes and controls; that provision does not apply, however, to practitioners licensed by law to prescribe or administer drugs and who manufacture drugs solely for use in the course of their professional practice.

21 U.S.C. 331(f) makes refusal to permit entry or inspection as authorized by Section 374 a prohibited act.

The district courts of the United States are given jurisdiction by 21 U.S.C. 332, for cause shown, to restrain violations of certain provisions of Section 331, including Section 331(f).

21 U.S.C. 333 provides that any person who violates a provision of 21 U.S.C. 331 shall be imprisoned for not more than one year or fined not more than $1,000, or both, unless certain specified exceptions apply; it also provides additional penalties for second offenses.

On February 10, 1975, Consumer Safety Officer Allen R. Halper visited petitioner's office, presented an official notice of inspection (Pet. App. 32a) to a nurse on duty and explained the purpose of his visit. The nurse advised investigator Halper that Dr. Daley had hours on Wednesday and Thursday from 10:00 a.m. until 4:00 p.m. The nurse declined to provide any information with regard to petitioner's operations or any related information, and she further indicated that all information with respect to Dr. Daley would have to be obtained from her lawyers (Pet. App. 4a).

Thereafter, another inspection was planned for a day on which the nurse indicated Dr. Daley maintained office hours. On February 27, 1975, Consumer Safety Officers John E. Klemmer and Thomas D. Gardine visited petitioner's office to attempt to conduct an inspection. The officers identified themselves to a nurse as FDA investigators, showed their credentials, and issued a notice of inspection (Pet. App. 33a). The inspectors asked to speak to Dr. Daley, but the nurse refused to allow them to enter the reception area. She advised the officers that Dr. Daley was not in the office that day and indicated that they would have to speak to the doctor's attorneys (Pet. App. 4a).

On February 28, 1975, the day following the second attempted inspection, petitioner brought this action seeking broad relief as follows: (1) a declaration that FDA lacks authority and jurisdiction to investigate, inspect, "or otherwise enforce" the provisions of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 301, *et seq.*, against her for her conduct in preparing, prescribing and administering approved drugs or combinations thereof in the course of her medical practice; and (2) an injunction restraining respondents from investigating, inspecting, or otherwise enforcing the provisions of the Act against her for such conduct (Pet. 8-9).

The district court characterized the complaint as aimed at preventing FDA from any further attempts to conduct inspections of Dr. Daley's office (Pet. App. 9a). It concluded that a controversy sufficiently ripe for adjudication did not exist between the parties, and granted respondent's motion for summary judgment dismissing the complaint (Pet. App. 17a-18a).

In reaching its decision, the court applied the guidelines set forth in *Abbott Laboratories* v. *Gardner*, 387 U.S. 136. It noted that *Abbott Laboratories* set forth a two-part test for determining if pre-enforcement relief from agency action should be given. The test requires the "evaluation of 'both the fitness of the issues for judicial decision and the hardship to the parties of withholding court consideration.' " The first portion of the test itself consists of two parts: whether the issues raised are purely legal in nature and whether the challenged agency action is final (Pet. App. 12a).

The district court noted that the only action taken by FDA had been to serve two notices of inspection, and concluded that while the issue raised appeared to be purely legal—that is, FDA's authority under 21 U.S.C. 374(a) to inspect a physician's office—there was no final action upon whose legality the court could pass. The court noted that no inspection had been conducted, and that it was reluctant to anticipate what future action, if any, FDA might take.

The district court also considered the hardship to the parties of withholding court consideration, and determined that the present case was distinguishable on its facts from *Abbott Laboratories*. Specifically, it found that petitioner in the present case, unlike petitioners in *Abbott Laboratories*, was not required to take any positive action to comply with FDA regulations since "the ball, so to speak, is in FDA's court" (Pet. App. 14a). Further, equitable relief was not needed because, if FDA sought to enjoin

petitioner's refusal to permit inspection, petitioner would have an opportunity at that time to justify her refusal. Alternatively, if a criminal proceeding were brought under 21 U.S.C. 333(a) for refusal to permit inspection, petitioner could raise FDA's lack of authority to conduct the inspection as a defense. The court disposed of petitioner's contention that she should not be required to test FDA's authority in a criminal proceeding, using two lines of reasoning. First, it held that there was no indication that FDA intended to prosecute petitioner for refusals to permit FDA inspection; second, it noted that courts have held in parallel situations that good-faith non-compliance, occurring while issues of governmental authority to issue administrative summonses are being disputed, cannot serve as a basis for prosecution (Pet. App. 15a-17a).

The court of appeals affirmed (Pet. App. 1a-6a), stating that it agreed with the district court that there does not yet exist a sufficient case or controversy on which to found declaratory or injunctive relief. Noting that FDA had done no more than to appear on two occasions and request permission to inspect, the court concluded that it was impossible to predict which of a number of possible future actions FDA would take, if any. It reviewed the prerequisites for relief set forth in *Abbott Laboratories* and its companion cases,[4] and concluded "all that appellant here suffers is the tentative possibility of a future inspection." The requirement that the need for equitable relief be "more than remote or speculative" had not, it held, been met (Pet. App. 5a-6a).

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[4] *Toilet Goods Assn.* v. *Gardner*, 387 U.S. 158; *Gardner* v. *Toilet Goods Assn.*, 387 U.S. 167.

ARGUMENT

Petitioner contends (Pet. 27-52) that an actual controversy exists between the parties, and that the courts below erred in applying the standards set forth in *Abbott Laboratories* for determining whether agency action is ripe for judicial review. She urges that the district court should proceed to determine her claim for declaratory and injunctive relief to prevent FDA from any further attempts to conduct, pursuant to 21 U.S.C. 374(a), an inspection of her office.

Petitioner argues that the issue for resolution here is purely a legal one, and that final agency action has taken place. This final agency action consists of FDA's interpretation of its Section 374 inspection authority, as well as its attempts to inspect petitioner's offices. Petitioner further argues that she suffers harm from this agency action because of the possibility of criminal prosecutions both for refusing future inspection and for having refused past inspections. Alternatively, she would suffer injury to her reputation if FDA brought civil proceedings, pursuant to 21 U.S.C. 332, to require petitioner to permit inspection. Petitioner urges that the fact that FDA has conducted two inspections requires the conclusion that further inspections will be conducted (Pet. 46-52).

The court of appeals was, we submit, correct in concluding that declaratory and injunctive relief should be denied because the need for relief has not been shown to be "more than remote or speculative."

1. Declaratory and injunctive relief are not appropriate if the injury claimed is remote or conjectural. *Golden* v. *Zwickler*, 394 U.S. 103, 109-110; *Public Service Commission* v. *Wycoff Co.*, 344 U.S. 237, 240-241; *Maryland Casualty Co.* v. *Pacific Coal & Oil Co.*, 312 U.S. 270.

Petitioner's argument concerning her claimed injury involves a series of speculative assumptions that demonstrate the remoteness of her claim.

She contends that the undisputed fact of attempted inspections shows that FDA will again attempt an inspection. While past FDA behavior may bear on the likelihood of future conduct, petitioner, to support her claim for relief, must nonetheless show that there exists "some cognizable danger of recurrent violation, something more than the mere possibility which serves to keep the case alive." *United States* v. *W.T. Grant Co.*, 345 U.S. 629, 633. In the present case, FDA may well decide that, because of enforcement priorities, or because of further information obtained about petitioner or the drug Liefcort, or for other reasons, no further inspections are appropriate. As of this date, no further inspections have in fact been attempted. There is, therefore, only a "mere possibility" of future attempted inspections.

It should be noted that for Dr. Daley to be charged under 21 U.S.C. 331(f) with "refusal to permit entry or inspections as authorized by [21 U.S.C. 374]," FDA at a minimum would have to obtain a refusal from someone more clearly authorized to give the refusal on petitioner's behalf than the nurse who met FDA inspectors at the door of the office on February 10 and February 27, 1975. Further, FDA has routinely obtained an inspection warrant or a search warrant from a magistrate or district court before taking any further enforcement action with respect to a refusal of inspection. None of these events has taken place in this case.

Petitioner argues not only that the Court should assume that FDA officials will attempt future inspections, but that FDA will then take further action concerning the refused inspection that will injure petitioner. This line of argument involves the Court in further speculation. If petitioner

formally refused inspection, FDA would have several courses of action open to it. It could take no further action, it could attempt to negotiate a form of inspection agreeable to both FDA and petitioner, it could obtain and then seek enforcement of a warrant, it could ask the Department of Justice to seek injunctive relief against petitioner under 21 U.S.C. 332, or it could refer the matter to the Department of Justice with a recommendation that criminal proceedings under 21 U.S.C. 333 be brought (see Pet. App. 5a).

The first two courses of action would, of course, cause no injury to petitioner.

In the event that FDA sought an injunction under 21 U.S.C. 332 or sought to enforce a warrant, petitioner could raise her claims concerning FDA's lack of inspection authority as a defense. An adequate remedy at law is therefore available to petitioner to raise her claims, and injunctive relief for petitioner is inappropriate to the extent that it is based on a theory of harm to petitioner resulting from FDA civil enforcement of its inspection authority. It is hardly credible, in any event, that her reputation would be harmed, as she claims, by an FDA civil action against her, since the sole issue would be, in all likelihood, FDA's authority to inspect a physician's offices, not her method of conducting her practice.

FDA, as petitioner notes, could also bring a criminal action for any future[5] refusals to permit inspection, pursuant to 21 U.S.C. 333. It is pure speculation, however,

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[5]Petitioner also appears to have requested declaratory and injunctive relief from FDA actions relating to past refusals of inspection. Equitable relief is clearly inappropriate for this purpose, since petitioner suffers no harm from awaiting resolution of the legality of the past refusals in the context of an action by the government pursuant to 21 U.S.C. 332 or 333. Cf. *Federal Trade Commission* v. *Claire Furnace Co.*, 274 U.S. 160. See also discussion in *Younger* v. *Harris*, 401 U.S. 37, 43-44.

that FDA would choose, and the Department of Justice would approve, this method unless FDA had first attempted enforcement of a warrant or other civil remedies. Moreover, this Court has held that in actions for declaratory or injunctive relief with respect to future criminal prosecutions, plaintiff must demonstrate a "genuine threat" of prosecution. *Ellis* v. *Dyson*, 421 U.S. 426, 434-435; *Steffel* v. *Thompson*, 415 U.S. 452, 458-460; *id.* at 475-476 (Mr. Justice Stewart, joined by Mr. Chief Justice Burger, concurring). In the absence of such a threat, there is no case or controversy; mere fear of prosecution is not sufficient. *Ellis* v. *Dyson*, *supra*, 421 U.S. at 434-435. In this case, petitioner has failed to demonstrate that FDA has threatened her with criminal prosecution; her amended complaint states only that criminal prosecution is "possible" (Pet. App. 28a).

The district court therefore did not abuse its discretion in determining, on these facts, that the agency action had not reached a sufficiently definite form, and that petitioner's claim of harm was not sufficiently definite or immediate to warrant the granting of relief.

2. Petitioner relies upon *Abbott Laboratories*, *supra*, to support her claims. In that case, the agency action challenged was a regulation that had "a direct effect on the day-to-day business of all prescription drug companies * * * . * * * 'Either they must comply with the every time requirement [*i.e.*, the requirement that the established name of the drug accompany the proprietary name every time it appeared] and incur the costs of changing over their promotional material and labeling or they must follow their present course and risk prosecution.' " 387 U.S. at 152 (footnote omitted). Harm to petitioners as a result of withholding of judicial review was therefore shown. In the present case, by contrast, there is no requirement that

petitioner take any action in the absence of further action by FDA, and petitioner has not established the likelihood of such action.

The present case differs significantly from *Gardner* v. *Toilet Goods Assn.*, 387 U.S. 167, upon which petitioner also relies.[6] That case, like *Abbott Laboratories,* involved FDA regulations that were "self-executing, and [had] an immediate and substantial impact upon the respondents." 387 U.S. at 171. Failure to comply with the regulations carried substantial penalties. Unlike the present case, therefore, *Gardner* involved agency action requiring immediate

[6]Two additional cases cited by petitioner in support of her position (Pet. 36) are distinguishable since they involved agency action that had an immediate impact on plaintiffs' business and required affirmative action by plaintiffs. In *Independent Broker-Dealers' Trade Association* v. *Securities & Exchange Commission,* 442 F. 2d 132 (C.A. D.C.), certiorari denied, 404 U.S. 828, the court held reviewable an SEC "request" to the New York Stock Exchange that caused the exchange to abolish a form of commission formerly paid to plaintiffs. In *National Automatic Laundry and Cleaning Council* v. *Shultz,* 443 F. 2d 689 (C.A. D.C.), the court held ripe for review a letter of the Wage-Hour Administrator stating that the Fair Labor Standards Act applied to the council's thousands of members; failure to comply with this agency interpretation could have subjected companies to double damages, and in extreme cases to criminal liability.

The case is also distinguishable from *Doe* v. *Bolton,* 410 U.S. 179, cited by petitioner (Pet. 42). In that case the immediate impact of the abortion statute was to force the physician not to perform abortions which they would otherwise perform, unless they were willing to risk prosecution. In the present case, it is not clear that FDA will ever attempt another inspection or that, if it does, petitioner's refusal to comply will result in criminal sanctions; there is no present constraint on petitioner and no "direct threat of personal detriment." 410 U.S. at 188.

affirmative action by petitioners and imposing penalties for failure to take the action.[7]

3. The decision of the Court of Appeals for the Seventh Circuit in *Durovic* v. *Palmer,* 342 F. 2d 634, certiorari denied, 382 U.S. 820, is in agreement with the decision below. In *Durovic* the court refused to grant an injunction against future inspections similar to those of which petitioner complains here. See also *American Dietaids Co.* v. *Celebrezze,* 317 F. 2d 658 (C.A. 2), certiorari denied, 375 U.S. 896 (denying an injunction against certain methods of inspection in absence of showing of intention or threat to carry out additional inspections).

4. Since the court of appeals correctly held that petitioner's complaint is not ripe for review, there is no need to consider petitioner's argument (Pet. 52-60) that 21 U.S.C. 374(a) does not apply to inspections of physicians' offices, even for purposes of examining equipment and finished and

[7]The present case has more similarities with the agency action found not to be ripe for review in *Toilet Goods Assn.* v. *Gardner,* 387 U.S. 158. In that case this Court found that final regulations relating to color additives that set forth penalties for failure to permit inspection by FDA were not an appropriate subject for judicial review, in the absence of attempted enforcement by FDA. This Court noted that "[a]t this juncture we have no idea whether or when such an inspection will be ordered and what reasons the Commissioner will give to justify his order. * * * This is not a situation in which primary conduct is affected—when contracts must be negotiated, ingredients tested or substituted, or special records compiled. * * * [N]o advance action is required of cosmetics manufacturers * * *." *Id.* at 163-164.

Similarly, in this case, FDA has given no indication that inspection will be ordered or on what facts it would base its authority to carry out the inspection. "Primary conduct" of petitioner is not affected, since no advance preparation is required of petitioner.

unfinished materials.[8] This issue, even if ripe for judicial review, is not properly presented to this Court since it was not considered by the courts below.

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted.

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[8] In any event, the exception for practitioners to which petitioner refers applies only to the special authority contained in the second sentence of Section 374(a), dealing with inspections relating only to prescription drugs. The general inspection authority contained in the first sentence of Section 374(a) is not affected by the exception.